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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,357	04/28/2006	Samantha Louise Budd Haeberlein	056291-5282	4953
9629 7590 08/09/2007 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER
			1614	
			MAIL DATE	DELIVERY MODE
			08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,357	Applicant(s) BUDD HAEBERLEIN ET AL.	
	Examiner Kevin E. Weddington	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006 and 15 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4-28-06; 8-15-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-17 are presented for examination.

Applicants' information disclosure statements filed April 28, 2006 and August 15, 2006 have been received and entered.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples

- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a use of a compound of Formula (I), a sulfonamide derivative, for the treatment of diabetes and/or obesity.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the instant compounds are effective in treating all types of diabetes such as type 1, type2 and gestational.

The breadth of the claims

The claims are very broad and inclusive to all types of diabetes

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the ability of the compound to inhibit ACAT.

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Example I only shows the inhibitory activity of sulfamic acid [[2,4,6-tris(1-methylethyl)phenyl]acetyl-2,6-bis(1-methylethyl)phenyl ester against DGAT1, DGAT2 and ACAT.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the instant compounds are effective in the treatment of all types of diabetes such as type 1, type 2 and gestational. The level of experimentation needed to determine the effectiveness of the instant compounds to treat all types of diabetes is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-17 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of a compound of formula (I) or a pharmaceutically acceptable salt, does not reasonably provide enablement for a pro-drug or solvate of the compound of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention commensurate in scope with these claims.

The instant claims recite "The use of a compound of Formula (I) ... or a pharmaceutically acceptable salt, **pro-drug** or **solvate** thereof" wherein there is insufficient description in the specification regarding the **pro-drug** or **solvate** intended by the recitation. The term 'pro-drug' generally represents any type of ester, amide, active metabolite, residue, etc. of a compound, which is transformed to an active agent *in vivo*. In the instant case, the specification does not provide what 'pro-drug or solvate' of the compounds of formula (I) are intended. The structural formula in each claim is a specific structural representation having specific defined substituent groups. There is no disclosure regarding any solvate of the compounds of formula (I) disclosed in the specification. A 'pro-drug' is any compound which is pharmaceutically active *in vivo* when it undergoes transformation and the specification does not provide any disclosure of what these compounds might be that *in vivo* transform into the instantly claimed compound.

Claims 1-17 are not allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17 are rendered indefinite by the phrase "use of" which is not an acceptable claim language used in the U.S. Patent Office and is normally rejected under 35 U.S.C. 101, but since the Examiner understands the claims are "method of use", then the rejection is under 35 U.S.C. 112, second paragraph.

Claims 1-17 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by over EP 1,236,468 A1 of PTO-1449, hereby known as Cornicelli et al.

Cornicelli et al. teach sulfonylaminocarbonyl derivatives that are useful in the treatment of type II diabetes, and metabolic syndrome X which includes obesity, insulin resistance and impaired glucose tolerance as its associated complications (See the abstract). Note on page 54, line 17 discloses one of the applicants' preferred compound, sulfamic acid[[2,4,6-tris(1-methylethyl)phenyl]acetyl-2,6-bis(1-methylethyl)phenyl ester (same claims 12, lines 22-23 and claim 13 of applicants).

Clearly, the cited reference teaches the instant sulfonamide compounds of Formula (I) are known to treat type II diabetes and metabolic syndrome X. Note that obesity, insulin resistance, and impaired glucose tolerance is complications associated with metabolic syndrome X; therefore, these associated complications are inherently treated.

Clearly, the cited reference teaches every element or limitation in applicants' instant invention; therefore, applicants' instant invention is unpatentable.

Claims 1-17 are not allowed.


The reference listed on the enclosed PTO-892 is cited to the PG Pub of EP 1,236,468 A1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
August 5, 2007